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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/998,904	<b>Applicant(s)</b> GARNER ET AL.	
	<b>Examiner</b> Marjorie A. Moran	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-213 is/are pending in the application.
- 4a) Of the above claim(s) 11,13-21,23-36 and 58-202, 205-213 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,12,22,37-57,203 and 204 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/1/02; 12/8/03</u> | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-57 and 203-204, and species of methylation, determining a variation frequency from a mutation dataset, and adjusting a variation frequency for wild type genes in a paper filed 11/3/03 is acknowledged. The traversal is on the ground(s) that each of the groups relates to generating and using a predictiveness matrix, therefore a search for Group I would be the same as a search for all other groups. This is not found persuasive because while all groups do recite a variation predictive matrix, all the groups do not recite steps of generating a matrix AND steps of using the matrix. Further, while a search for any single group MAY overlap with a search for any other group, the searches are not necessarily the same. The recitation of different limitations and/or method steps in the various groups requires a different search for each group.

In response to applicant's comments with regard to rejoinder of species claims, rejoinder will be considered upon indication of allowable subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11, 13-21, 23-36, and 58-213 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in a paper filed 11/3/03..

An action on the merits of elected claims 1-10, 12, 22, and 37-57, 203 and 204, as they read on the elected species, follows.

***Information Disclosure Statement***

The IDS's filed 4/1/02 and 12/8/03 have been considered in full.

***Claim Objections***

Applicant is advised that should claim 40 be found allowable, claim 43 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. This is a LACK of WRITTEN DESCRIPTION rejection.

Claim 54 limits a computer program for performing the method of claim 1 to one called "SNIDE". The specification, on page 6, defines SNIDE as "Single Nucleotide variation Identification". On pages 26-27, the specification describes SNIDE as a "computational method and system" which comprises at least three steps including determination of "each possible nonsynonymous mutation" and "assignment of predictiveness". On page 28, the specification specifically discloses that the novel component of SNIDE "hinges on the statistical methodology" involved. Pages 30-31 of the specification repeatedly disclose use of a "SNIDE algorithm". However, the specification does not disclose any particular computer program, algorithm, or "statistical methodology" which maybe interpreted to be a computer program, anywhere. It is possible that the steps of pages 26-27 are "computer-implemented"; however, these appear to be general method steps and are not, per se, a "computer program". As the specification does not specifically describe a computer program or algorithm called SNIDE, claim 54 is rejected for lack of written description.

Claim 55 limits a computer program for performing the method of claim 1 to one called "SNooP". "SNooP" is defined on page 6 of the specification as a "single nucleotide polymorphism", seemingly equivalent to "SNP". There is no other definition or description of a computer program called SNooP anywhere in the instant specification, therefore claim 55 is rejected for lack of written description.

Claims 1-10, 12, 22, 37-57, and 203-204 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the prior art nor specification teaches how to obtain a variation or codon predictiveness matrix such that variations or polymorphisms may be predicted.

The prior art provides no guidance on how to obtain or create a variation or codon predictiveness matrix. The instant specification teaches, on pages 21-22, that statistical analysis may be used to determine the frequency of a *class* of mutations from a mutation database. The specification specifically discloses on page 21, paragraph 59 that for each mutation class, a predictive value was derived that encompasses the "likelihood" that a given point mutation will occur and the impact of that mutation. The specification does not teach how the "likelihood" is calculated nor how to determine the "impact" of the mutation. The specification teaches on page 22 that a "predictiveness value" is the *class's* frequency in a mutation database. The frequency of a class of mutations which appear in a database is not the same as *prediction* of the frequency (likelihood?) of a single (point) mutation. In addition, while the frequency of a mutation

in a database may be correlated to its “likelihood” of occurrence, mere frequency does not seem to include or be a determination of “impact”. The specification teaches that Table 1B (p. 23) is exemplary of a variation predictiveness matrix, but does not teach any specific method steps, statistical analysis, or algorithm for arriving at the “predictiveness” values of the Table. Page 25 and Figure 2 disclose calculation of a distribution of codon mutation *classes*, but are not exemplary of a variation predictiveness matrix from which SNP’s may be predicted. The specification further discloses SNIDE on pages 26-30. As set forth above, the specification does not disclose any particular computer program or algorithm for SNIDE. One pages 26-27, the specification teaches that SNIDE comprises several steps, none of which are recited in the instant claims.

It is noted that the specification particularly teaches, on page 28, that the “novel component” of the instant invention is the statistical method; however, the specification fails to disclose any particular statistical method or algorithm which results in a matrix for predicting SNPs or sequence “variations”. The level of skill in the art is acknowledged to be high. The level of unpredictability in predicting mutations/polymorphisms, specifically SNPs, is also high, as admitted on pages 1-3 of the instant specification. Given the high level of unpredictability in the art for predicting mutations, and the lack of guidance in either the prior art or the specification for how to do so, it would require undue experimentation even for one highly skilled in the art to obtain a variation predictiveness matrix suitable for predicting variations or

polymorphisms using the method steps recited in the claims. For these reasons, the claims are not enabled.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10, 22, 53, and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the dataset" in line 1. There is insufficient antecedent basis for this limitation in the claim. Parent claims 1 and 8 do not recite any dataset, therefore claim 9 is indefinite.

Claim 22 recites a limitation wherein a variation frequency is "further adjusted". Recitation of the term "further" implies that the variation frequency was previously adjusted; however parent claim 8 recites merely "calculating" a variation frequency. Claim 8 does not recite any "adjustment" subsequent to the calculation of the variation frequency, therefore it is unclear what is meant by the "further" adjustment of claim 22. For these reasons, claim 22 is indefinite. This rejection may be overcome by deleting the term "further" in line 1.

Claim 53 limits the method of claim 1 to be "affected" by a computer program. It is unclear what steps or steps are required to "affect" the method of claim 1 or what the computer program is intended to "affect" in the method of claim 1, therefore claim 53 is



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indefinite. As the indefiniteness may be due to a typographical error, this rejection may be overcome by replacing "affect" with --effect-- if such is consistent with applicant's intent.

Claim 54 limits a computer program to be "SNIDE". The specification, on page 6, defines SNIDE as "Single Nucleotide variation Identification". On pages 26-27, the specification describes SNIDE as a "computational method and system" which comprises at least three steps including determination of "each possible nonsynonymous mutation" and "assignment of predictiveness", but does not specifically define a computer program or algorithm to be SNIDE, as set forth above. It is unclear whether applicant intends claim 54 to limit the method of claim 1 to comprise further method steps; e.g. those of pages 26-27 or merely intends the steps of claim 1 to be computer-implemented, or intends the steps of claim 1 to comprise an algorithm, or intends some other limitation, therefore claim 54 is indefinite.

Claim 55 limits a computer program to be "SNooP". "SNooP" is defined on page 6 of the specification as a "single nucleotide polymorphism", seemingly equivalent to "SNP". There is no other definition or description of a computer program called SNooP anywhere. See above. As one skilled in the art would not be able to ascertain what the metes and bounds of a "SNooP" computer program are intended to be based on the disclosure of the specification and claims, claim 55 is indefinite.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

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